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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 485,245	03 27 2000	ALISON HOPKINS	28911 36128	1697

7590 05 01 2002

MARSHALL O'TOOLE GERSTEIN
MURRAY & BORUN
6300 SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO, IL 60606-6402

EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED 05 01 2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/485,245

Applicant(s)

HOPKINS ALISON

Examiner

Cynthia B Wilder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Final Action*

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FINAL ACTION

1. The request filed on March 21, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/485,245 is acceptable and a CPA has been established. An action on the CPA follows.
2. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Claim Rejections - 35 USC § 103

3. Claims 1- 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suganuma et al. (Analytical Biochemistry January 20, 1995), and further in view of Shen et al (EP 0 726 310 August 14, 1996) and further in view of Hoeltke et al. (5,814,502, effective filing date October 1994). Regarding claims 1, 2 and 4, Suganuma et al. also teach a labeling composition comprising a random mixture of oligonucleotides which are 5 mers to 11 mers (page 605, col. 2, lines 36 and 37). Suganuma et al. teach wherein the composition further comprise a polymerase enzyme, a supply of nucleotides for chain extension, a labeled nucleotide and buffer (page 606, lines 1-10). The composition Suganuma et al. differ from that of the claimed invention in that the references do not

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teach wherein a dye and/or stabilizer is added to the composition. In a composition similar to that of Suganuma et al., Shen et al. teach wherein the nucleic acid composition is present in a dry state. Shen et al. also teach wherein the composition comprise a stabilizer along with a polymerase enzyme and a supply of nucleotides for chain extension (page 6, lines 3-7 and 22). Shen et al. do not expressly teach the incorporation of a dye. However, the use of dyes as labeling agents are routinely practiced in the art. For example, Hoeltke et al. teach a labeling composition similar to that of Suganuma et al. and Shen et al. comprising a random mixture of oligonucleotides, a polymerase enzyme, a supply of nucleotides, a dye and buffer wherein the dye aids in the visualization of the polynucleotide product generated with the composition (col. 2, lines 32-60 and col. Example 1). In view of the foregoing, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to add a stabilizer to the labeling composition of Suganuma et al. for the expected benefits taught by Shen et al. that a stabilizing agent prevents or delays the loss of a composition's biological activity as a result of storage over time (page 4, lines 8-10). One of ordinary skill in the art would have been motivated further to add a dye to the composition for labeling as taught by Hoeltke et al. for the obvious benefit of visualizing a polynucleotide generated with the composition.

Regarding claim 3, Suganuma et al. teach, wherein the random mixture is of 6 mer oligonucleotides (page 605, col. 2, lines 36 and 37).

Regarding claim 5, Suganuma et al. teach a method of making a labeled probe for a nucleic acid template, wherein the method comprises the steps of providing a nucleic acid template and

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labeling composition and incubating the nucleic acid template under chain extension conditions with the labeling composition to produce labeled probes (bottom of page 605, beginning at line 38 to page 606, lines 11-11).

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suganuma et al. in view of Shen et al. in view of Hoeltke et al. (5,814,502, effective filing date October 1994) and further in view of Strategene (January 1997). Regarding claim 6, Suganuma et al. in view of Shen et al. teach a labeling composition and method of making a labeled probe comprising a number of method steps wherein the labeled compositions comprises a random mixture of oligonucleotides which are 6 mers to 8-mers, and said composition present in a dry state. The labeling composition of the disclosure differs from that of the references in that the references do not expressly teach the concentration of the random mixture of oligonucleotides. However the optimal contents range would have been determined by the practitioner based on desired properties of the random oligonucleotides, desired lengths of the random oligonucleotides and desired results. For example, in a method for labeling nucleic acid, Hoeltke et al. teach a random mixture of oligonucleotides wherein the concentration range of approximately 15 to 80 OD/ml is selected for the various random primers which are 6-mers to 15- mers. Hoeltke et al. further teach that depending on the primer length, the optimal contents range will change (col. 2, lines 55-60 and col. 3, lines 38-42). Strategene teaches a labeling composition comprising mixture of oligonucleotides which are 7-mers to 8-mers wherein the mixture of oligonucleotides are present at a concentration of about 1 OD/ml to 10 OD/ml. In view of the foregoing, it would have been obvious to one of ordinary skill in the

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art that the concentration range of the random mixture of oligonucleotide may vary based the practitioner's preference as well as the length of the primers as suggested by Hoeltke et al.

Conclusion

5. No claims are allowed. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

April 25, 2002


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

4/30/02

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